



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-508F]

Final Adjusted Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2020

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: This final order establishes the final adjusted 2020 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, VA 22152, Telephone: (571) 362-3261.

SUPPLEMENTARY INFORMATION:

Legal Authority

Section 306 of the Controlled Substances Act (CSA) (21 U.S.C. 826) requires the Attorney General to establish aggregate production quotas (APQ) for each basic class of controlled substances listed in schedules I and II and for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. The Attorney General has delegated this

function to the Administrator of the Drug Enforcement Administration (DEA) pursuant to 28 CFR 0.100.

Background

DEA published the 2020 established APQ for controlled substances in schedules I and II and for the assessment of annual needs (AAN) for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine in the *Federal Register* on December 2, 2019. 84 FR 66014. DEA is committed to preventing and limiting diversion by enforcing laws and regulations regarding controlled substances and the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, while meeting the legitimate medical, scientific, and export needs of the United States. This notice stated that the Administrator would adjust, as needed, the established APQ in 2020 in accordance with 21 CFR 1303.13 and 21 CFR 1315.13.

In response to the public health emergency declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, DEA published the final order titled “Adjustments to Aggregate Production Quotas for Certain Schedule II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine and Pseudoephedrine for 2020” on April 10, 2020. (85 FR 20302). While the adjustments were effective immediately, all interested persons were invited to comment on or object to the adjustments on or before May 11, 2020.

The 2020 proposed adjusted APQ for controlled substances in schedules I and II and AAN for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine were subsequently published in the *Federal Register* on September 1, 2020, (85 FR 54414), after consideration of the criteria outlined in that notice. All interested persons were invited to comment on or object to the proposed APQs and AANs on or before October 1, 2020.

Comments Received

DEA received five timely comments and one untimely comment in response to the

April *Federal Register* notice and nine comments in response to the September *Federal Register* notice from patients, DEA-registered entities, and non-DEA entities. The comments included appreciation of DEA's response to the public health emergency, concerns about potential drug shortages, interference with doctor-patient relationships, and comments outside the scope of this final order.

Issue: Commenters expressed appreciation of DEA's flexibility in responding to the nationwide public health emergency declared by the Secretary of HHS on January 31, 2020, by adjusting APQ for select schedule II controlled substances and list I chemicals.

DEA Response: DEA acknowledges the expressions of appreciation to changes in the APQ and AAN. The adjustments to select schedule II controlled substances and list I chemicals occurred after DEA consulted with HHS and determined the utilization rates for these drugs substantially increased due to the treatment regimens for ventilator patients stricken with the Coronavirus Disease of 2019 (COVID-19) compared to the previously estimated annual consumption rates. While the estimates from HHS provided a wide range in the number of patients that would require ventilation treatment due to COVID-19, DEA could, under 21 CFR 1303.13 and 1315.13, adjust the APQ and AAN for schedule II controlled substances and list I chemicals, respectively, to ensure manufacturing activities cover the upper range of the estimate could occur in a timely manner. DEA highlights factor 21 CFR 1303.13(b)(5) specifically, which allowed the Acting Administrator to increase the APQ and AAN for select controlled substances and list I chemicals to meet additional estimated medical needs as determined by HHS due to the unforeseen emergency caused by the COVID-19 pandemic.

Issue: Commenters expressed general concerns that decreasing the APQ of controlled substances could lead to shortages of controlled substance medications.

One DEA-registered entity submitted a comment requesting the APQ for hydrocodone (for sale) and oxycodone (for sale) be sufficient to provide for the estimated

medical, scientific, research, and industrial needs of the United States, for export requirements, and for the establishment and maintenance of reserve stocks.

DEA Response: DEA sets APQ in a manner to ensure that the estimated medical, scientific, research, industrial needs of the United States, lawful export requirements, and for the establishment and maintenance of reserve stocks. As discussed in both notices for adjustments, any adjustments to the APQ for controlled substances is based on factors set forth in 21 CFR 1303.13. In the event of a shortage, the CSA provides a mechanism under which DEA will, in appropriate circumstances, increase quotas to address shortages. 21 U.S.C. 826(h). Under 21 U.S.C. 826(h)(1), after receiving a request to address a shortage, DEA has 30 days to complete review of the request and determine whether adjustments are necessary to address the shortage. If adjustments are necessary, DEA is required to increase the APQ and individual production quotas to alleviate the shortage. *Id.* If DEA determines adjustments are not necessary, DEA is required to “provide a written response detailing the basis for the . . . determination.” *Id.* In addition to what Section 826(h)(1) requires, when DEA is notified of an alleged shortage, DEA will confer with the U.S. Food and Drug Administration and relevant manufacturers regarding the amount of material in physical inventory, current quota granted, and the estimated legitimate medical need, to determine whether a quota adjustment is necessary to alleviate any factually valid shortage.

In accordance with 21 CFR 1303.13, DEA considered the comments for hydrocodone (for sale) and oxycodone (for sale), and the Acting Administrator determined the proposed adjusted 2020 APQs for these substances as published in the *Federal Register* on September 1, 2020, (85 FR 54414), are sufficient to meet the current 2020 estimated medical, scientific, research, and industrial needs of the United States, and to provide for adequate reserve stock.

Issue: DEA received comments of general concerns alleging decreases to the APQ interfered with doctor-patient relationships.

DEA Response: In determining the APQ, DEA considers prescriptions that have been

issued. However, DEA does not interfere with doctor-patient relationships. Doctors authorized to dispense controlled substances are responsible for adhering to the laws and regulations set forth under the CSA, which requires doctors to only write prescriptions for a legitimate medical need. DEA is responsible for enforcing controlled substance laws and regulations, and is committed to ensuring an adequate and uninterrupted supply of controlled substances in order to meet the demand of legitimate medical, scientific, and export needs of the United States.

Untimely Comment Issue: The DEA received one comment from a DEA-registered entity for previously established value of the 2020 AAN for pseudoephedrine (for conversion), requesting an increase because the established AAN is not adequate to cover the commenter's new projected need for 2020.

DEA Response: The comment was received in between the comment periods for the two notices of adjustment. Even though the comment was outside the comment period that ended on May 11, 2020, DEA considered this comment as part of the second comment period ending on October 1, 2020, when setting the final 2020 AAN.

Out of Scope Comments: DEA received comments on issues outside the scope of this final order. The comments were general in nature and raised issues of specific medical illnesses, medical treatments, and medication costs, and therefore, are outside of the scope of this Final Order for 2020 and do not impact the original analysis involved in finalizing the 2020 APQ.

Analysis for Final Adjusted 2020 Aggregate Production Quotas and Assessment of Annual Needs

In determining the final adjusted 2020 APQ and AAN, DEA has considered the above comments relevant to this Final Order for calendar year 2020, along with the factors set forth in 21 CFR 1303.13 and 21 CFR 1315.13, in accordance with 21 U.S.C. 826(a). DEA has also considered other relevant factors, including the 2019 year-end inventories, initial 2020

manufacturing and import quotas, 2020 export requirements, actual and projected 2020 sales, research and product development requirements, additional applications received, and the extent of any diversion of the controlled substance in the class. Based on all of the above, the Acting Administrator is adjusting the 2020 APQ for the following: increases for Amphetamine (for sale) and Methamphetamine, based on the data received since the publication of the 2020 proposed adjustment for APQ and AAN in the *Federal Register* on September 1, 2020 (85 FR 54414); increases for Crotonyl Fentanyl, Ethylone, and Isotonitazene due to the publication of their schedule I temporary controlled status; and increases for Etonitazene due to additional manufacturers entering the reference standard market. This final order reflects those adjustments.

Pursuant to the above, the Acting Administrator hereby finalizes the 2020 APQ for the following schedule I and II controlled substances and the 2020 AAN for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

<i>Basic Class</i>	Final Revised 2020 Quotas
	(g)
<i>Temporarily Scheduled Substances</i>	
Crotonyl fentanyl	25
Ethylone	25
Isotonitazene	25
Schedule I	
1-[1-(2-Thienyl)cyclohexyl]pyrrolidine	20
1-(1-Phenylcyclohexyl)pyrrolidine	15
1-(2-Phenylethyl)-4-phenyl-4-acetoxypiperidine	10
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	30
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	30
1-Benzylpiperazine	25
1-Methyl-4-phenyl-4-propionoxypiperidine	10
1-[1-(2-Thienyl)cyclohexyl]piperidine	15
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	30
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	30
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	30
2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C-P)	30

2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	100
2-(4-Bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36)	30
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	30
2-(4-Chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82)	25
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	30
2-(4-Iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)	30
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25
2,5-Dimethoxy-4-(n)-propylthiophenethylamine	25
2,5-Dimethoxyamphetamine (DMA)	25
2-(4-Ethylthio-2,5-dimethoxyphenyl)ethanamine (2C-T-2)	30
2-(4-(Isopropylthio)-2,5-dimethoxyphenyl)ethanamine (2C-T-4)	30
3,4,5-Trimethoxyamphetamine	30
3,4-Methylenedioxyamphetamine (MDA)	55
3,4-Methylenedioxymethamphetamine (MDMA)	50
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	40
3,4-Methylenedioxy-N-methylcathinone (methyldone)	40
3,4-Methylenedioxypyrovalerone (MDPV)	35
3-Fluoro-N-methylcathinone (3-FMC)	25
3-Methylfentanyl	30
3-Methylthiofentanyl	30
4-Bromo-2,5-dimethoxyamphetamine (DOB)	30
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	25
4-Chloro- α -pyrrolidinovalerophenone (4-chloro- α -PVP)	25
1-(4-Cyanobutyl)-N-(2-phenylpropan-2-yl)-1 H-indazole-3-carboximide (4CN-Cumyl-Butinaca)	25
4-Fluoroisobutyryl fentanyl	30
4-Fluoro-N-methylcathinone (4-FMC; Flephedrone)	25
4-Methyl-N-ethylcathinone (4-MEC)	25
4-Methoxyamphetamine	150
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25
4-Methylaminorex	25
4-Methyl-N-methylcathinone (mephedrone)	45
4-Methyl- α -ethylaminopentiophenone (4-MEAP)	25
4-Methyl- α -pyrrolidinohexiophenone (MPHP)	25
4-Methyl- α -pyrrolidinopropiophenone (4-MePPP)	25
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]phenol	50
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]phenol (cannabicyclohexanol or CP-47,497 C8-homolog)	40
5F-CUMYL-PINACA	25
5F-EDMB-PINACA	25

5F-MDMB-PICA	25
5F-AB-PINACA; N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide	25
5F-CUMYL-P7AICA; (1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-pyrrolo[2,3-b]pyridine-3-carboximide)	25
5F-ADB; 5F-MDMB-PINACA (methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	30
5F-AMB (methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate)	30
5F-APINACA; 5F-AKB48 (N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide)	30
5-Fluoro-PB-22; 5F-PB-22	20
5-Fluoro-UR144, XLR11 ([1-(5-fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone	25
5-Methoxy-3,4-methylenedioxyamphetamine	25
5-Methoxy-N,N-diisopropyltryptamine	25
5-Methoxy-N,N-dimethyltryptamine	25
AB-CHMINACA	30
AB-FUBINACA	50
AB-PINACA	30
ADB-FUBINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide)	30
Acetorphine	25
Acetyl Fentanyl	100
Acetyl-alpha-methylfentanyl	30
Acetyldihydrocodeine	30
Acetylmethadol	25
Acryl Fentanyl	25
ADB-PINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide)	50
AH-7921	30
Allylprodine	25
Alphacetylmethadol	25
Alpha-Ethyltryptamine	25
Alphameprodine	25
Alphamethadol	25
Alphaprodine	25
Alpha-Methylfentanyl	30
Alpha-Methylthiofentanyl	30
Alpha-Methyltryptamine (AMT)	25
Alpha-Pyrrolidinobutiophenone (α -PBP)	25
Alpha-Pyrrolidinoheptaphenone (PV8)	25
Alpha-Pyrrolidinohexanophenone (α -PHP)	25
Alpha-Pyrrolidinopentiophenone (α -PVP)	25
Aminorex	25
Anileridine	20
APINACA, AKB48 (N-(1-adamantyl)-1-pentyl-1H-	25

indazole-3-carboxamide)	
Benzethidine	25
Benzylmorphine	30
Betacetylmethadol	25
Beta-Hydroxy-3-methylfentanyl	30
Beta-Hydroxyfentanyl	30
Beta-Hydroxythiofentanyl	30
Betameprodine	25
Betamethadol	4
Betaprodine	25
Bufotenine	15
Butylone	25
Butyryl fentanyl	30
Cathinone	40
Clonitazene	25
Codeine methylbromide	30
Codeine-N-oxide	192
Cyclopentyl Fentanyl	30
Cyclopropyl Fentanyl	20
Cyprenorphine	25
Desomorphine	25
Dextromoramide	25
Diampromide	20
Diethylthiambutene	20
Diethyltryptamine	25
Difenoxin	9,200
Dihydromorphine	753,500
Dimenoxadol	25
Dimepheptanol	25
Dimethylthiambutene	20
Dimethyltryptamine	50
Dioxaphetyl butyrate	25
Dipipanone	25
Drotebanol	25
Ethylmethylthiambutene	25
Etonitazene	25
Etorphine	30
Etoxadine	25
Fenethylamine	30
Fentanyl related substances	600
FUB-144	25
FUB-AKB48	25
FUB-AMB, MMB-Fubinaca, AMB-Fubinaca	25
Furanyl fentanyl	30
Furethidine	25
Gamma Hydroxybutyric Acid	29,417,000
Heroin	45
Hydromorphanol	40

Hydroxypethidine	25
Ibogaine	30
Isobutyryl Fentanyl	25
JWH-018 and AM678 (1-Pentyl-3-(1-naphthoyl)indole)	35
JWH-019 (1-Hexyl-3-(1-naphthoyl)indole)	45
JWH-073 (1-Butyl-3-(1-naphthoyl)indole)	45
JWH-081 (1-Pentyl-3-(1-(4-methoxynaphthoyl)indole)	30
JWH-122 (1-Pentyl-3-(4-methyl-1-naphthoyl)indole)	30
JWH-200 (1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole)	35
JWH-203 (1-Pentyl-3-(2-chlorophenylacetyl)indole)	30
JWH-250 (1-Pentyl-3-(2-methoxyphenylacetyl)indole)	30
JWH-398 (1-Pentyl-3-(4-chloro-1-naphthoyl)indole)	30
Ketobemidone	30
Levomoramide	25
Levophenacylmorphan	25
Lysergic acid diethylamide (LSD)	40
MAB-CHMINACA; ADB-CHMINACA (<i>N</i> -(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1 <i>H</i> -indazole-3-carboxamide)	30
MDMB-CHMICA; MMB-CHMINACA(methyl 2-(1-(cyclohexylmethyl)-1 <i>H</i> -indole-3-carboxamido)-3,3-dimethylbutanoate)	30
MDMB-FUBINACA (methyl 2-(1-(4-fluorobenzyl)-1 <i>H</i> -indazole-3-carboxamido)-3,3-dimethylbutanoate)	30
MMB-CHMICA (AMB-CHMICA); Methyl-2-(1-(cyclohexylmethyl)-1 <i>H</i> -indole-3-carboxamido)-3-methylbutanoate	25
Marihuana	3,200,000
Mecloqualone	30
Mescaline	25
Methaqualone	60
Methcathinone	25
Methoxyacetyl fentanyl	30
Methyl-desorphine	5
Methyldihydromorphine	25
Morpheridine	25
Morphine methylbromide	5
Morphine methylsulfonate	5
Morphine-N-oxide	150
MT-45	30
Myrophine	25
NM2201; Naphthalen-1-yl 1-(5-fluoropentyl)-1 <i>H</i> -indole-3-carboxylate	25
N,N-Dimethylamphetamine	25
Naphyrone	25
N-Ethyl-1-phenylcyclohexylamine	25
N-Ethyl-3-piperidyl benzilate	10
N-Ethylamphetamine	24

N-Ethylhexedrone	25
N-Ethylpentylone, ephylone	30
N-Hydroxy-3,4-methylenedioxyamphetamine	24
N-Methyl-3-Piperidyl Benzilate	30
Nicocodeine	25
Nicomorphine	25
Noracymethadol	25
Norlevorphanol	55
Normethadone	25
Normorphine	40
Norpipanone	25
Ocfentanil	25
Ortho-fluorofentanyl, 2-fluorofentanyl	30
Para-chloroisobutyryl fentanyl	30
Para-fluorofentanyl	25
Para-fluorobutyryl fentanyl	25
Para-methoxybutyryl fentanyl	30
Parahexyl	5
PB-22; QUPIC	20
Pentedrone	25
Pentylone	25
Phenadoxone	25
Phenampromide	25
Phenomorphane	25
Phenoperidine	25
Pholcodine	5
Piritramide	25
Proheptazine	25
Properidine	25
Propiram	25
Psilocybin	30
Psilocyn	50
Racemoramide	25
SR-18 and RCS-8 (1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole)	45
SR-19 and RCS-4 (1-Pentyl-3-[(4-methoxy)-benzoyl]indole)	30
Tetrahydrocannabinols	384,460
Tetrahydrofuranlyl fentanyl	15
Thebacon	25
Thiafentanil	25
Thiofentanyl	25
THJ-2201 ([1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone)	30
Tilidine	25
Trimeperidine	25
UR-144 (1-pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone	25

U-47700	30
Valeryl fentanyl	25
Schedule II	
1-Phenylcyclohexylamine	15
1-Piperidinocyclohexanecarbonitrile	25
4-Anilino-N-phenethyl-4-piperidine (ANPP)	934,956
Alfentanil	3,260
Alphaprodine	25
Amobarbital	20,100
Amphetamine (for conversion)	14,137,578
Amphetamine (for sale)	44,330,000
Bezitramide	25
Carfentanil	20
Cocaine	73,090
Codeine (for conversion)	3,225,000
Codeine (for sale)	35,341,292
Dextropropoxyphene	35
Dihydrocodeine	156,713
Dihydroetorphine	25
Diphenoxylate (for conversion)	14,100
Diphenoxylate (for sale)	770,800
Ecgonine	78,439
Ethylmorphine	30
Etorphine hydrochloride	32
Fentanyl	934,956
Glutethimide	25
Hydrocodone (for conversion)	1,250
Hydrocodone (for sale)	33,997,285
Hydromorphone	3,512,651
Isomethadone	30
Levo-alphaacetylmethadol (LAAM)	25
Levomethorphan	30
Levorphanol	31,730
Lisdexamfetamine	21,000,000
Meperidine	1,119,862
Meperidine Intermediate-A	30
Meperidine Intermediate-B	30
Meperidine Intermediate-C	30
Metazocine	15
Methadone (for sale)	25,619,700
Methadone Intermediate	27,673,600
Methamphetamine	1,224,109
[678,878 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 505,231 grams for methamphetamine mostly for conversion to a schedule III product; and 40,000 grams for methamphetamine (for sale)]	
Methylphenidate	57,438,334
Metopon	25
Moramide-intermediate	25

Morphine (for conversion)	3,376,696
Morphine (for sale)	33,756,703
Nabilone	62,000
Norfentanyl	25
Noroxymorphone (for conversion)	22,044,741
Noroxymorphone (for sale)	376,000
Opium (powder)	250,000
Opium (tincture)	530,837
Oripavine	33,010,750
Oxycodone (for conversion)	725,998
Oxycodone (for sale)	65,667,554
Oxymorphone (for conversion)	28,204,371
Oxymorphone (for sale)	658,515
Pentobarbital	25,850,000
Phenazocine	25
Phencyclidine	35
Phenmetrazine	25
Phenylacetone	40
Piminodine	25
Racemethorphan	5
Racemorphan	5
Remifentanyl	3,000
Secobarbital	172,100
Sufentanyl	4,000
Tapentadol	13,447,541
Thebaine	59,284,070
List I Chemicals	
Ephedrine (for conversion)	100
Ephedrine (for sale)	4,756,000
Phenylpropanolamine (for conversion)	14,100,000
Phenylpropanolamine (for sale)	16,590,000
Pseudoephedrine (for conversion)	1,000
Pseudoephedrine (for sale)	200,382,900

The Acting Administrator further proposes that APQ for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 remain at zero.

Timothy J. Shea,
Acting Administrator.

